

JUN 19 2002

1021567

StimuCath Continuous Nerve Block Set

510(k) Premarket Notification

SECTION 3. 510K SUMMARY

Submitter:	Arrow International Inc. 2400 Bernville Road Reading, PA 19605
Contact person:	William G. McLain Manager, Regulatory Submissions and Quality Systems Phone: 610-378-0131 Fax: 610-478-3188 E-mail: bill.mclain@arrowintl.com
Date summary prepared:	5/8/02
Device trade name:	StimuCath™ Continuous Nerve Block Set
Device common name:	Peripheral nerve stimulating catheter and needle
Device classification name:	CAZ, Class II at 21 CFR 868.5140, Anesthetic Conduction Kit
Legally marketed devices to which the device is substantially equivalent:	K801912: Arrow TheraCath® Epidural Catheter K831715: HDC Corp Neurotrac K840287: Contiplex Continuous Nerve Block Set
Description of device:	<p>The StimuCath™ Continuous Nerve Block Device is an anesthesia conduction catheter that is electrically conductive. Using peripheral nerve stimulation, the clinician can locate specific nerves or nerve plexuses for continuous nerve block anesthesia or analgesia.</p> <p>The StimuCath™ is available sterile in a kit with the necessary accessories required to perform the procedure and fix the catheter in place.</p>
Intended use of the device:	The Arrow StimuCath™ Continuous Nerve Block Set permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques. It is indicated for use up to 72 hours.
Technological characteristics:	The proposed device has similar technological characteristics to the predicate devices including design, packaging, sterilization and labeling.

Performance tests:

The following tests were performed to demonstrate substantial equivalence:

- Holding strength of Snap-Lock™ adapter to catheter
- Snap force of Snap-Lock™
- Leak test (positive pressure)
- Flow rate
- Biocompatibility tests
- Power and current density calculations
- Clinical study

Conclusions:

The results of the laboratory tests, calculations and the clinical study demonstrate that the device is substantially equivalent to the legally marketed predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Arrow International Inc
c/o Mr. William G. McLain
Manager, Regulatory Submissions and Quality Systems
2400 Bernville Road
Reading, PA 19605

Re: K021567
StimuCath™ Continuous Nerve Block Set
Regulation Number: 868.5140
Regulation Name: Anesthesia Conduction Kit
Regulatory Class: II (two)
Product Code: 73 CAZ
Dated: May 8, 2002
Received: May 13, 2002

Dear Mr. McLain:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in dark ink, appearing to read "Donna-Bea Tillman", is written over the typed name.

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 13. INDICATIONS FOR USE STATEMENT

510(k) Number (if known):

K021567

Device Name:


StimuCath™ Continuous Nerve Block device (SCNB).

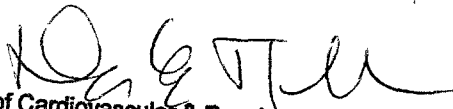
Indications for Use:

The Arrow StimuCath™ Continuous Nerve Block Set permits placement of catheters next to nerves and nerve plexuses for continuous nerve block anesthesia or analgesia techniques for periods not exceeding 72 hours.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use 
(Per 21 CFR 801.109)


Division of Cardiovascular & Respiratory Devices
510(k) Number K021567